



8-23 8707 Rec'd PCT/PTO 20 AUG 2004
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRANSMITTAL FORM

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Applicant(s): Mandel et al.
Serial No.: 10/031,143
Filed: January 13, 2002
For: HEARTBURN TREATMENT
Examiner: Jiang, Shaojia A.
Art Unit: 1617
Confirmation No.: 8659

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Customer No.: 27623

Attorney Docket No.: C75101

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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2 SEP 2004

Dear Sir:

Legal Staff
International Division

We are enclosing:

1. Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b), including a curtesy copy of a previously submitted Preliminary amendment;
2. Firm check in the amount of \$1,330.00;
3. Transmittal letter in duplicate; and
4. Postcard.

Please charge any additional fees or credit any such fees, if necessary to Deposit Account No. 01-0467 in the name of Ohlandt, Greeley, Ruggiero & Perle. A duplicate copy of this sheet is attached.

Respectfully submitted,

Charles N. J. Ruggiero
Reg. No. 28,468
Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
One Landmark Square, 10th Floor
Stamford, Connecticut 06901-2682
(203) 327-4500

Date: August 20, 2004

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Certificate No. **EV 451128038 US**, service under 37 CFR §1.10 and is addressed to: Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Attention: Office of Petitions on August 20, 2004.

Mary R. Charles

(Typed name of person mailing paper)

(Signature of person mailing paper)



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED
UNINTENTIONALLY UNDER 37 CFR 1.137(b)

Dear Sir:

The above-identified application became abandoned for failure to file a timely response in reply to an Office Action mailed on May 21, 2003, which set a three (3) month period for reply. The mailing date of the Notice of Abandonment was February 11, 2003.

Applicant hereby petitions for revival of the above-identified application pursuant to 37 CFR 1.137(b), which requires the following:

- (1) a Petition fee;
- (2) a Reply and/or Issue Fee;

Serial No.: 10/031,143
Art Unit: 1617

- (3) a Terminal Disclaimer with disclaimer fee - required for all utility and plant patent applications filed before June 8, 1995, and for all design applications; and
- (4) a Statement that the entire delay was unintentional.

Applicant herewith includes the following: (1) a Petition fee of \$1,330.000 applicable for a large entity under 37 CFR 1.179(m); (2) a Reply to the above-noted Office Action in the form of a Response below; (3) no Terminal Disclaimer, as the above-identified application was filed after June 8, 1995; and (4) a Verified Statement below.

VERIFIED STATEMENT

Applicant hereby states that the delay in filing a response to the Office Action dated May 21, 2003 until the filing of this petition, under 37 CFR 1.137(b), was unintentional.

Applicant further declares that all statements made herewith of my own knowledge are true and all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon or any patent to which this verified statement is directed.

RESPONSE

In an Office Action mailed on May 21, 2003, the Examiner noted that the application did not contain an abstract of disclosure as required by 37 CFR 1.72(b).

In response, Examiner is respectfully invited to review applicant's file to note that a Preliminary Amendment was filed on January, 3, 2002, and included an abstract; a copy of which is hereby attached.

Therefore, in view of the above amendment and the attached abstract, Applicant's specification complies with 37 CFR 1.72(b). Examiner is respectfully requested to reconsider and withdraw the objection.

In the Action, claim 7 was rejected under 35 U.S.C. § 112, second paragraph for Applicant's use of the term "ANC" in claim 7 of the specification on the basis that the term was a trade name.

Applicant respectfully notes that "ANC" is a common term used in the art to mean an "Acid Neutralizing Capacity" amount of compound or substance. Applicant's use of the term in the claim 7, as his own lexicographer, is not intended to identify or designate a source of goods, but to clarify to a skilled artisan, the necessary values of antacid concentration to enable the disclosure. Evidence of this description may be found on page 5, line 16 -17 of the specification.

Accordingly, since the term "ANC" as used by Applicant does not designate or describe a source of goods, Examiner's rejection of indefiniteness on the basis of 35 U.S.C. § 112, 2nd paragraph, should be withdrawn.

In the Action, Claims 1-12 were rejected as being obvious in view of Phillips (U.S. Patent No. 5,840,737, hereinafter "Phillips"). Specifically, claims 1-3, and the abstract (Col. 1, lines 27-29; and Col. 12, line 38) of the reference were cited as disclosing a method for treating gastric acid disorders including (GERD) or heartburn.

Applicant respectfully traverses the rejection because the Action fails to establish a *prima facie* basis for obviousness under 35 U.S.C. § 103.

To establish a *prima facie* case of obviousness three basic criteria must be met. First, there must be a suggestion or motivation in either of the references, or in the knowledge generally available in the art, to modify the reference or teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or (references when combined), must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and reasonable expectation of success must be found in the prior art and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

Phillips does not teach or suggest to one of ordinary skill in the art that a combination of an effective amount of proton pump inhibitor (PPI) and an effective acid-neutralizing amount of alkali metal bicarbonate salt would treat Gastroesophageal Reflux Disease (GERD) or heartburn. First, Phillips as a whole focuses on the prophylactic prevention of upper GI bleeding in critically ill patients. It is directed to reducing stress-related gastric mucosal damage (Col. 1, lines 35-37; Col. 2, lines 39-40), not the relief of heartburn symptoms.

Second, while the Action notes that Phillips discloses a known use of omeprazole for the short-term treatment of GERD (Col. 1, lines 27-29), this disclosure is insufficient to suggest to a skilled artisan that a *specific selection* of a PPI-bicarbonate *combination* would provide rapid onset and prolonged relief of heartburn as disclosed by claim 1 of the present invention. Moreover, the cited sections of Phillips (Col. 1, lines 27-29; Col. 12, line 38; and claims 1-3), fail to support the use of an "effective amount" of proton inhibitor and "effective acid neutralizing" amount of alkali metal bicarbonate salt for the specific treatment of heartburn.

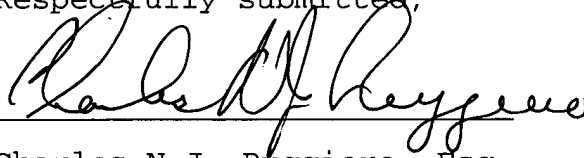
Given that Phillips fails to disclose or suggest an effective PPI-bicarbonate combination for heartburn treatment and is primarily directed to the treatment upper GI bleeding, a skilled artisan, without more, would have little expectation of success in obtaining rapid-onset of heartburn symptoms using the methods described.

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Art Unit: 1617

Accordingly, for at least the above reasons, a *prima facie* case of obviousness has not been established. Therefore, Applicants respectfully request that this rejection under 35 U.S.C. § 103 be reconsidered and withdrawn.

August 20, 2004

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

Charles N.J. Ruggiero, Esq.
Registration No. 28,468
Attorney for the Applicants
Ohlandt, Greeley, Ruggiero &
Perle, L.L.P.
One Landmark Square
Stamford, CT 06901-2682
(203) 327-4500

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AUG 26 2004

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PATENT

ATTORNEY'S DOCKET NUMBER C75101

TRANSMITTAL LETTER TO THE U.S. DESIGNATED OFFICE
(DO/US) - ENTRY INTO NATIONAL STAGE UNDER 35 USC 371

INTERNATIONAL APP. NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/18896	12 July 2000	12 July 1999

TITLE OF INVENTION
Heartburn Treatment

RECEIVED
SEP 21 2004

APPLICANT(S) FOR DO/US
Kenneth G. MANDEL, Steven M. JOHNSON

OFFICE OF PETITIONS

Box PCT
Commissioner of Patents and Trademarks
Washington, D.C. 20231
ATTENTION: DO/US

PRELIMINARY AMENDMENT

Dear Sir:

Preliminary to calculation of the filing fees and examination of the above noted application, entrance of the following remarks and amendments into the record is respectfully requested.

In the Claims:

Please amend the following claims:

5. (Amended) The method according to Claim 1 wherein the bicarbonate is sodium or potassium bicarbonate or a mixture thereof.

REMARKS

This Preliminary Amendment is being made upon entry of International Application No. PCT/US00/18896 in the U.S. §371 national phase of prosecution. Claim 5 has been amended to remove multiple dependency and to conform to US Practice. Claims 1 to 12 are in the application.

A marked version of the amended claims accompanies this paper.

An abstract on a separate sheet of paper accompanies this request.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



Dara L. Dinner
Attorney for Applicant
Registration No. 33,680

GLAXOSMITHKLINE
Corporate Intellectual Property UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5017
Facsimile (610) 270-5090
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MARKED UP VERSION OF CLAIMS TO SHOW CHANGES MADE

3. (Amended) The method according to [any one of Claims 1 to 4] Claim 1 wherein the bicarbonate is sodium or potassium bicarbonate or a mixture thereof.

ABSTRACT

The present invention is directed to the use of an alkali metal salt of a bicarbonate, preferably sodium bicarbonate, and an effective amount of a proton pump inhibitor in combination for the treatment of heartburn symptoms.